

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 287.1006		SERIAL NO.: 10/631,371	
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): RALPH A. HEASLEY, et al.			
				FILING DATE: July 31, 2003		GROUP: 1615	
<div style="float: left; border: 1px solid black; border-radius: 50%; padding: 5px; text-align: center; width: 100px; height: 100px; line-height: 100px;"> O I P E AUG 12 2005 TRADEMARK OFFICE </div> <div style="clear: both;"></div>							
U.S. PATENT DOCUMENTS							
EXAMINER:		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
CA							
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
CB							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
BP	CC	Pilbrant A, Schannong M, Vessman J., "Pharmacokinetics and bioavailability of tranexamic acid." <u>Eur J Clin Pharmacol</u> 1981;20:65-72.					
	CD	Puigdemivol E, Carral M, Moreno J, et al., "Pharmacokinetics and absolute bioavailability of intramuscular tranexamic acid in man." <u>Int J Clin Pharmacol Therapy Toxicology</u> 1985;23:298-301.					
	CE	Eriksson O, Kjellman H, Pilbrant A, et al., "Pharmacokinetics of tranexamic acid after intravenous administration to normal volunteers." <u>Eur J Clin Pharmacol</u> 1974;7:375-380.					
	CF	Andersson I, Nilsson I, Colleen S, et al., "Role of urokinase and tissue activator in sustaining bleeding and the management thereof with EACA and AMCA." <u>Ann NY Acad Sci</u> 1968;146:642-658.					
	CG	Dowd N, Karski J, Cheng D, et al. "Pharmacokinetics of Tranexamic Acid during Cardiopulmonary Bypass." <u>Anesthesiology</u> 2002;97:390-99.					
	CH	Kaller H, "Enterale Resorption, Verteilung und Elimination von 4-Aminomethylcyclohexancarbonsäure (AMCHA) und α-Aminocapronsäure (ACS) beim Menschen." <u>Naunyn-Schmiedeberg's Arch. Pharmacol. Exp Path.</u> 256: 160-169 (1967).					
	CI	Andersson L, Eriksson O, Hedlund P, et al. "Special Considerations with Regard to the Dosage of Tranexamic Acid in Patients with Chronic Renal Diseases." <u>Urological Research</u> 6, 83-88 (1978).					
	CJ	Nilsson I, "Clinical pharmacology of aminocaproic and tranexamic acids." <u>J Clin Pathol</u> , 33, Suppl (Roy Coll Path), 14, 41-47.					
	CK	Melander B, Gliniecki G, Granstrand B, et al. "Biochemistry and Toxicology of Amikapron®: The Antifibrinolytically Active Isomer of AMCHA. (A comparative Study with α-Aminocaproic Acid)" <u>Acta pharmacol. et toxicol.</u> 1965, 22, 340-352.					
	CL	Longstaff C, "Studies on the mechanisms of action of aprotinin and tranexamic acid as plasmin inhibitors and antifibrinolytic agents." <u>Blood Coagulation and Fibrinolysis</u> , 5, 537-542. (1994)					
↓	CM	Dockeray C, Sheppard B, Daly L, et al., "The fibrinolytic enzyme system in normal menstruation and excessive uterine bleeding and the effect of tranexamic acid." <u>Eur. J. Obstet. Gynecol. Reprod. Biol.</u> , 24 (1987) 309-318.					
BP	CN	Mohri H., "High Dose of Tranexamic Acid for Treatment of Severe Menorrhagia in patients with von Willebrand Disease." <u>Journal of Thrombosis and Thrombolysis</u> 14(3), 255-257, (2002).					
EXAMINER				DATE CONSIDERED			
/Blessing Fubara/				08/16/2006			
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Sheet 2 of 4

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	DB						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
BF	DC	Preston J, Cameron I, Adams E, et al. "Comparative study of tranexamic acid and norethisterone in the treatment of ovulatory menorrhagia." <u>British Journal of Obstetrics and Gynaecology</u> , May 1995, Vol. 102, pp. 401-406.					
	DD	Bonnar J, Sheppard B. "Treatment of menorrhagia during menstruation: randomized controlled trial of ethamsylate, mefenamic acid, and tranexamic acid." <u>British Medical Journal</u> 1996;313:579-82.					
	DE	Nilsson L, Rybo G. "Treatment of Menorrhagia with an Anti-fibrinolytic Agent, Tranexamic Acid (AMCA) A Double Blind Investigation." Nilsson, Lennart and Rybo, Göran, <u>Acta obst. Et gynec. scandinav.</u> 46, 572, (1967); 572-580					
	DF	Vermylen J, Verhaegen-Declercq M, Verstraete M, et al. "A Double Blind Study of the Effect of Tranexamic Acid in Essential Menorrhagia." From the Laboratory of Coagulation-Proteolysis, Department of Medicine, University of Leuven, Belgium. 583-587.					
	DG	Callender S, Warner G, Cope E. "Treatment of Menorrhagia with Tranexamic Acid. A Double-blind Trial." <u>British Medical Journal</u> , 1970, 4, 214-216.					
	DH	Andersch B, Milsom I, Rybo G. "An Objective Evaluation of Flurbiprofen and Tranexamic Acid in the treatment of Idiopathic Menorrhagia." <u>Acta Obstet Gynecol Scand</u> 67:645-648, 1988.					
	DI	Milsom I, Andersson K, Andersch B, et al. "A comparison of flurbiprofen, tranexamic acid, and a levonorgestrel-releasing intrauterine contraceptive device in the treatment of idiopathic menorrhagia." <u>Am J Obstet Gynecol</u> 1991;164:879-83.					
	DJ	Gleeson N, Buggy F, Sheppard B, et al. "The effect of tranexamic acid on measured menstrual loss and endometrial fibrinolytic enzymes in dysfunctional uterine bleeding." <u>Acta Obstet Gynecol Scand</u> 1994; 73:274-277.					
	DK	Lee J, Hahn P, Van Dijk J, et al. "Treatment of Menorrhagia with Tranexamic Acid." <u>J Soc Obstet Gynaecol Can</u> 2000;22(10):794-8.					
	DL	Edlund M, Andersson K, Rybo G, et al., "Reduction of menstrual blood loss in women suffering from idiopathic menorrhagia with a novel antifibrinolytic drug (Kabi 2161)." <u>British Journal of Obstetrics and Gynaecology</u> 1995, Vol. 102, pp 913-917.					
V	DM	Winkler U. "The effect of tranexamic acid on the quality of life of women with heavy menstrual bleeding." <u>European Journal of Obstetrics & Gynecology and Reproductive Biology</u> 99 (2001) 238-243.					
BF	DN	Rybo G., "Tranexamic acid therapy - effective treatment in heavy menstrual bleeding. Clinical update on safety." <u>Therapeutic Advances</u> ISSN 0964-0673 Issue 4. (1991)					
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BF	EA	6	1	1	3	9	4	3	09/05/00	Okada et al.	424	457		
BF	EB	5	8	5	8	4	1	1	01/12/99	Nakagami et al.	424	489		
BF	EC	5	8	0	7	5	8	3	09/15/98	Kristensen et al.	424	489		
BF	ED	5	6	2	2	6	5	7	05/22/97	Takada et al.	264	4.32		
BF	EE	4	2	5	8	0	3	0	03/24/81	Sasaki et al.	424	94		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EF													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
BF	EG	Berntorp E. "No Increased Risk of Venous Thrombosis in Women Taking Tranexamic Acid." <u>Thromb Haemost</u> 2001; 86: 714-5.												
	EH	Bekassy Z, Astedt B. "Treatment with the Fibrinolytic Inhibitor Tranexamic Acid - Risk for Thrombosis?" <u>Acta Obstet Gynecol Scand</u> 1990; 69: 353-354.												
	EI	Mannucci P., "Hemostatic Drugs." <u>Drug Therapy</u> , Vol. 339, No. 4, p. 245-253 (1998).												
	EJ	Wellington K, Wagstaff A., "Tranexamic Acid - A Review of its Use in the Management of Menorrhagia." <u>Adis Drug Evaluation</u> , Drugs 2003;63(13):1417-1433.												
	EK	Dunn C, Goa K. "Tranexamic Acid - A Review of its Use in Surgery and Other Indications." <u>Adis Drug Evaluation</u> , Drugs 1999 Jun; 57 (6): 1005-1032.												
	EL	"An evidence-based guideline for the management of heavy menstrual bleeding. Working Party for Guidelines for the Management of Heavy Menstrual Bleeding." <u>NZ Med J</u> 1999; 112: 174-7.												
	EM	Lethaby A, Farquhar C, Cooke I. "Antifibrinolytics for heavy menstrual bleeding." <u>Cochrane Database of Syst Rev</u> 2002; (4).												
↓	EN	Lakhani K, Marsh M, Purcell W. "Uterine artery blood flow parameters in women with dysfunctional uterine bleeding and uterine fibroids: the effects of tranexamic acid." <u>Ultrasound Obstet Gynecol</u> 1998;11:283-285												
BF	EO	Ong, Y., et al., "Menorrhagia in von Willebrand disease successfully treated with single daily dose tranexamic acid." <u>Haemophilia</u> (1998), 4, 63-65												
	EP													
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U.S. PATENT DOCUMENTS																			
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE						
BP	FA	4	4	8	3	8	6	7	11/20/84	Svahn et al.	424	279							
BP	FB	2004	00	0	6	0	2	1	01/08/04	Rojkjaer	514	12							
	FC																		
	FD																		
	FE																		
	FF																		
	FG																		
FOREIGN PATENT DOCUMENTS																			
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION						
													YES	NO					
	FH																		
	FI																		
	FJ																		
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)																			
BP	FK	Watzman, M. and Bonnar, J., "Effects of Tranexamic Acid on the Coagulation and Fibrinolytic Systems in Pregnancy Complicated by Placental Bleeding", New Toxicology for Old Arch. Toxicol., Suppl. 5, 214-220 (1982).																	
BP	FL	Cyclokapron® Package Insert. Pharmacia & Upjohn. Revised October 2000.																	
BP	FM	Cyklokapron® Package Insert. Pharmacia Canada, Inc. Mississauga, Ontario. (Nov. 2002)																	
	FN																		
	FO																		
	FP																		
	FQ																		
	FR																		
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SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
XANO/40SERIAL NO.
10/631,371INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

APPLICANT
Heasley et al.FILING DATE
July 31, 2003GROUP
1615

(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A.A						
	A.B						
	A.C						
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	A.H						
	A.I						
	A.J						
	A.K						

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
BF	A.L	EP 0 998 916 A1	5-10-2000	EP	A61K	9/00	No
BF	A.M	GB 2 073 019 A	10-14-1981	UK	A61K	7/22	No
	A.N						
	A.O						
	A.P						
	A.Q						

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

BF	A.R	Patent Abstracts of Japan Publication No. JP 06219942, <u>GELATIN CAPSULE PREPARATION MIXED WITH TRANEXAMIC ACID</u> , Published 8-09-1994
BF	A.S	Patent Abstracts of Japan Publication No. JP 07206660, <u>EXTERNAL PREPARATION FOR SKIN</u> , Published 8-08-1995
BF	A.T	Patent Abstract of Japan Publication No. JP 09124878, <u>GEL COMPOSITION</u> , Published 5-13-1997

EXAMINER

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DATE CONSIDERED

08/16/2006

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Substitute Disclosure Form (PTO-1449)

1/25/05

Sheet 2 (B) of 2

SUBSTITUTE FORM PTO-1449
(MODIFIED)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
XANO/40

SERIAL NO.
10/631,371

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APPLICANT
Heasley et al.

(Use several sheets if necessary)

(37 CFR 1.98(b))

FILING DATE
July 31, 2003

GROUP
1615

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	B.A						
	B.B						
	B.C						
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	B.F						
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	B.J						
	B.K						

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	B.L						
	B.M						
	B.N						
	B.O						
	B.P						
	B.Q						

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

BP	B.R	Patent Abstracts of Japan Publication No. JP 09255542, <u>COMPOSITION FOR ORAL CAVITY APPLICATION</u> , Published 9-30-1997
BP	B.S	Patent Abstracts of Japan Publication No. JP 57059847, <u>4-AMINOMETHYLCYCLOHEXANECARBOXYLIC ACID DERIVATIVE</u> , Published 4-10-1982
BP	B.T	International Search Report, Mailed January 7, 2005

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/Blessing Fubara/

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Substitute Disclosure Form (PTO-1449)

7/31/03

Sheet 1 (A) of 1

SUBSTITUTE FORM PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. XANO/40		SERIAL NO.							
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98(b))				APPLICANT Heasley et al.									
				FILING DATE July 28, 2003		GROUP Unknown							
U.S. PATENT DOCUMENTS													
EXAMINER INITIAL		PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	A.A	5	2	2	9	1	3	5	07/20/93	Philippon et al.	424	494	11/22/91
BF	A.B	5	2	4	2	3	3	7	09/07/93	Greenwood	476	10	11/02/90
BF	A.C	5	6	5	0	1	7	4	07/22/97	Muhammad et al.	424	494	03/07/95
BF	A.D	6	0	6	6	3	3	9	05/23/00	Stark et al.	424	489	11/25/97
BF	A.E	6	4	3	3	2	1	5	08/13/02	Jung	560	220	03/01/00
BF	A.F	6	5	4	8	0	8	4	04/15/03	Leonard et al.	424	482	09/09/99
BF	A.G	6	5	5	1	6	1	6	04/22/03	Notario et al.	424	464	10/13/99
	A.H												
	A.I												
	A.J												
	A.K												
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	A.M												
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